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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,203	01/09/2006	Gideon Dreyfuss	PENN-0882	6769
26259 LICATA & TY	7590 10/01/200 RRELL P.C.	8	EXAMINER	
66 E. MAIN ST		JEAN-LOUIS, SAMIRA JM		
MARLTON, NJ 08053			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			10/01/2008	ELECTRONIC

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

	Application No.	Applicant(s)				
Office Action Occurrence	10/532,203	DREYFUSS ET AL	L.			
Office Action Summary	Examiner	Art Unit				
	SAMIRA JEAN-LOUIS	1617				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence ad	dress			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	<b>J.</b> nely filed the mailing date of this co D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merit						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	i3 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-8</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdraw	vn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) <u>1-8</u> are subject to restriction and/or ele	ection requirement.					
Application Papers						
9) The specification is objected to by the Examiner						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign	priority under 35 LLS C. 8 119(a)	-(d) or (f)				
a) ☐ All b) ☐ Some * c) ☐ None of:	priority aridor 00 0.0.0. 3 110(a)	(4) 51 (1).				
1. ☐ Certified copies of the priority documents	s have been received.					
3. Copies of the certified copies of the prior	ity documents have been receive	ed in this National	Stage			
application from the International Bureau	application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.						
Attach mant (a)						
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:						
Paper No(s)/Mail Date	o) LI Other					

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claims 1-3 are drawn to a method of treating a neurodegenerative disease or disorder comprising administering an effective amount of a compound that replaces or enhances the function of SMN to alleviate or reduce a phenotype of cells with low SMN protein levels.
- II. Group II, claims 4 and 8 are drawn to a method of identifying a psychopharmacological agent comprising contacting a test cell, which has low SMN protein levels, with a test agent and detecting an ability of said agent to alleviate or reduce a phenotype of said cells, wherein the ability of said agent to alleviate or reduce a phenotype of said cells is indicative of said agent being a psychopharmacological agent.
- III. Group III, claims 5-6 are drawn to a method of treating a psychiatric disease or disorder comprising administering an effective amount of a psychopharmacological agent identified by the method of claim 4.

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IV. Group IV, claim 7 is drawn to a psychopharmacological composition comprising a psychopharmacological agent identified by the method of claim 4 and a pharmaceutically acceptable carrier.

The inventions listed as Groups I, II, III, and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings. Whether or not any specific technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature", should be considered with respect to novelty and inventive step.

In this instant application, the common technical feature in both groups is the compound that replaces or enhances the function of SMN to alleviate or reduce a phenotype of cells with low SMN protein levels. These compounds cannot be said to be a special technical feature under PCT Rule 13.2 because these compounds are shown in the prior art.

In this case, Herbert et al. (U.S. 5,576,328, cited by applicant and filed on an IDS 1449) teach compounds that replace or enhance the function of SMN to alleviate or reduce a phenotype of cells with low SMN protein levels including compound 25 that is taught by Herbert et al. (see abstract and col. 2, lines 1-19). As a result, no special technical features exist among the different groups because the inventions in Groups I, II, III, and IV fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

## Species Election

This application contains claims directed to more than one species of the generic invention. These species either possess divergent structures and/or contrastingly different chemical and physical properties. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species listed below do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same special technical feature among the different species.

The species are as follows:

Applicant is required to elect a particular compound of formula I, II, or III that replaces or enhances the function of SMN. Alternatively applicant may elect a particular compound listed in claim 3.

Applicant is required to elect a particular neurodegenerative disease or disorder to be treated in the method of group I.

Applicant is required to elect a particular test agent to be utilized with the method of group II.

Applicant is required to elect a particular psychiatric disease or disorder to be treated in the method of group III.

Applicant is required to elect a particular psychopharmacological agent to be utilized with the method of group IV.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims 1-8 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is also reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

No telephone call was made due to the complexity of the election/restriction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

09/23/08

/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1617